MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Thursday, December 12, 2002
9:44 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
SHEILA D. BURKE
AUTRY O.V. "PETE" DeBUSK
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CAROL RAPHAEL
ALICE ROSENBLATT
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DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

<u>AGENDA ITEM:</u> Paying for new technologies --Chantal Worzala

MR. HACKBARTH: Next on the agenda is paying for new technology. So we're moving from our discussions about specific update factors to a conceptual issue that we've discussed numerous times recently. In fact, Chantal, given that in this case I think we've got a draft chapter, as I recall, in the book that is pretty well developed and which we spent a lot of time talking about, I think we ought to be able to move through it pretty quickly. So your assistance would be appreciated.

DR. WORZALA: Understood. This afternoon we're going to talk about how Medicare pays for new technologies in its prospective payment system. As Glenn mentioned, we talked about this before and you've seen quite a lot of the material previously, and I'll try to be quick.

When dealing with new technologies, Medicare must balance two goals, paying adequately to ensure beneficiary access to care, and being a prudent purchaser. This is an old problem. It's been debated since the inpatient PPS was first implemented in 1983. We do, however, have new solutions in the form of inpatient add-on payments and outpatient new technology provisions that have been added in recent years.

My presentation has two distinct parts. First I'll look at what Medicare is doing, and then I will look at what other payers are doing.

You've seen this slide previously. I think we've talked about the content many times. The notion is that a PPS makes a fixed payment for a bundled service. This gives providers considerable freedom to determine the mix of inputs, which allows many technologies to enter without any formal decisionmaking. The incentive here is to use new technologies that decrease cost, but it may slow the adoption of costly new technologies.

There are some constraints to prospective payment. I'll focus on the third one here, which is that prospective payment relies on coding and cost report data systems that involve multiple actors and take time to provide reliable information for setting payment rates. Therefore, the payment systems can sometimes be slow to incorporate the cost of new technology, potentially providing a disincentive to adopt them.

We should note that CMS has taken steps to accelerate these processes in the past year or two. However, some manufacturers and providers suggest they're still too slow.

On the opposite side, however, it is difficult to find reliable and credible alternative sources of information for setting payment rates. Also some would argue that lags in setting payment for new technologies provides time to evaluate the technology's merits and to establish a price reflecting potential efficiency gains from using the technology over time.

Congress added specific mechanisms to pay for new technologies in both the inpatient and outpatient payment systems. While these special payment provisions are beneficial in that they help to ensure beneficiary access to new technologies and steer additional payments to hospitals using new technologies, they do have some drawbacks that are listed here. We've discussed these before. I won't go through them in detail.

On this slide are the provisions of the inpatient new technology add-on payments. They were described in detail in your briefing papers. Implementation of the add-on payments started in fiscal year 2003, so just about two months ago. There is a single drug, a treatment for sepsis, that is currently eligible for add-on payments. Most observers do feel that the eligibility criteria are fairly stringent. They encompass newness, clinical, and cost considerations.

I won't go through the payment provisions and rather narrow in a little bit on the clinical criteria. Most observers, including our expert panel participants feel that additional payments for new technology should really be limited to truly new technologies that provide a clear clinical benefit. Consequently, I want to walk you through the clinical criteria for the inpatient add-on payments.

In broad brush, to be eligible for add-on payments a new technology must substantially improve, relative to technologies previously available, the diagnosis or treatment of beneficiaries. CMS payment and coverage staff collaborated to specify what that might mean, how it might be interpreted. They give examples such as providing a new treatment option altogether, or a treatment option applicable to patients that cannot be treated using existing technologies; technologies that offer a new ability to diagnose a medical condition or to make a diagnosis earlier, either for everyone or for a subpopulation not helped by existing technologies.

Another example would be a technology that results in improved clinical outcomes such as reduced mortality, reduced rate of complications, decreased future hospitalizations or physician visits, or decreased symptoms such as pain or bleeding, or reduced recovery time.

It's important to remember that these clinical criteria are applied to a technology that is submitting an application for additional payment. This is not by any means a criteria for coverage.

Now I'm going to switch to the outpatient PPS. I think we've talked about this many, many times. I won't go through the details here of either the new technology APCs or the pass-through payments. I'm sure you're thankful for that.

I will, however, on the next slide, look at the criteria that are applied to technologies seeking additional pass-through payment. They are different for medical devices versus drugs or biologicals. Those are the three kinds of technologies that are eligible for pass-through payments, medical devices, drugs, and biologicals.

For medical devices, the criteria include newness, cost, and clinical benefit, but clinical criteria are very similar to those applicable to the inpatient add-on payments with the exception of some things targeted at physical attributes of the device that might make it a sort of generational change.

By contrast, for drugs and biologicals, only the newness and the cost criteria apply. We would argue that this represents an inconsistency in the treatment of technologies across drugs and biologicals versus medical devices within the outpatient PPS, so that effectively medical devices are subject to more stringent criteria than drugs and biologicals.

Similarly, there's an inconsistency in the treatment of the drugs and biologicals across payment systems with clinical criteria applying on the inpatient side but not on the outpatient side.

Given the need to target new technology payments to those technologies that are in some sense the most important, and our desire to achieve consistency of treatment within and across payment systems, we propose the following draft recommendation for your consideration.

The Secretary should introduce clinical criteria for eligibility of drugs and biologicals to receive pass-through payments. This recommendation should have no impact on spending since the pass-through payments are budget neutral.

At this point I will shift, unless there are questions, to a slightly different topic, which is the results of our research on the approaches taken by other payers in paying for new technology, and the expert panel that we convened on paying for new technology in Medicare. Again, you have seen these results previously. You've seen the final reports from our contractor.

What we have here is a list of approaches taken by other payers. I don't think I will go through them in detail except to note a couple of things, which is that everyone that we interviewed said that they do invest considerable resources in tracking technology, understanding the medical evidence regarding new technology's benefit, and they use that information. They look at costs as well. They spend a lot of time trying to understand cost effectiveness analysis, and really use that information to bolster their positions in negotiations for price when they're purchasing new technologies.

Our discussion in the expert panel indicated that none of the strategies adopted by other payers is in fact easily adapted to Medicare because the program faces some unique constraints. The program is large; it covers over 40 million beneficiaries, so it has a large impact on the health care market. If Medicare were to adopt competitive bidding or other selective approaches, it could greatly affect the financial status of specific manufacturers, and also potentially have an impact on future innovation.

In addition, other payers often follow Medicare in setting their payment rates, so that leads to an even greater influence on the market.

Second, the Medicare program acts as an insurer, reimbursing hospitals and physicians for their services. As currently constructed, Medicare cannot negotiate directly with manufacturers to set prices for technologies. However, we would note that there is a competitive bidding demo underway and that may open up some new possibilities.

I think I will close here on saying that CMS really has limited administrative capacity and resources, financial resources to engage in the kind of the strategies employed by other purchasers, who as I mentioned, invest heavily in tracking and analyzing technological advances.

Although the specific strategies that were identified by other purchasers are not easily adopted by Medicare, they do embody a common concept that we think could prove useful to the program. In paying for new technologies, other payers strive for value-based purchasing. That is, they limit purchases to technologies that have demonstrated clinical benefit, or they try to, and they make judgments about whether the additional benefits of a technology outweigh the additional costs.

When we convened the expert panel they expressed often that Medicare showed pursue value-based purchasing, however, there was no specific approach that was put forth for how that could be done or any agreement on how it could be done. We do know that there are serious methodological issues that arise with value-based purchasing: what is the level of evidence that's needed? What are the scope of cost and benefits that you need to include when assessing value? What threshold value would you set when evaluating a technology? Those are just a few of the questions that arise.

We do know that there are other challenges for the Medicare program in pursuing value-based purchasing. Past attempts by Medicare to introduce cost effectiveness analysis into the coverage process have been met with resistance.

Despite these challenges, value-based purchasing provides a mechanism to better balance the goals of paying adequately for new technology to ensure beneficiary access to care, and being a prudent purchaser. I think the introduction of clinical criteria for these additional new technology payments moves in that direction, but we may perhaps be able to move even further.

I'll stop there.

DR. NEWHOUSE: Chantal, I don't have any disagreement with what you just said, but I have a very strong disagreement with what's in the written materials to us, and it's on value-based purchasing where you suggest that that leads toward paying in accordance with the level of the benefit. We don't follow that elsewhere in the program or in general.

The water I get at my house has a very large benefit to be, but I don't pay anything close to the benefit it has to me. And that's generally true through the economy. So while I'm happy to take clinical considerations into account in thinking about coverage, I don't want to think about payment in the same way.

Further, I think, as you know I have for a certain, I hope fairly limited class of devices and drugs, if we get there, I have suggested a rate of return cap and you, I think I would have said just took one particular tack on that and dismissed it too quickly on administrative grounds which is -- first of all, let me say where I think it's needed, and I don't think it's needed elsewhere. It's one where devices on patent, there's no good clinical substitute, and there's a demonstrated benefit, and there's a non-trivial Medicare share. So Medicare is basically facing something that it really wants to have and no alternative supplier.

I think that in that situation Medicare can't agree to pay whatever the manufacturer names. Who knows how we would calculate value, so I don't think your criterion works either. But you say, we can't do this because we would have to figure out the costs that were specific to that product. I don't know that we have to do it that way . We could, for example, use the manufacturer's Medicare book of business which would be readily ascertainable.

I can find a lot of problems with that, but I can find a lot of problems in any procedure we use here. I think there is a real problem in this area and I don't think this is -- we can certainly -- we will face it.

The only other comment I had on the draft is an optics problem. You have a discussion in the text box of who will benefit from new technology payments and there's no mention of patients. I's all framed as which providers will benefit. If I were a patient reading this I would wonder how am I benefiting from all this. I think you might want to recast that.

DR. WORZALA: Poorly titled. I'll correct that.

MS. RAPHAEL: I just had one comment which is, I think whatever we do we have to recommend some increase in the infrastructure in CMS to deal with this, because we keep saying they have limited administrative ability, therefore they can't do X, they can't do Y. It's unlikely this would ever comes to pass. This is a very important issue. However we end up tackling it, it's not going to happen unless there is some infrastructure and expertise that can take this on on a sustained basis.

DR. WOLTER: This is probably more looking out ahead over several years, but in addition to technology related decisions around specific devices or biologics, if we look at things like clinical knowledge systems and how over time they may imbed clinical knowledge, clinical pathways, help us with drug alerts, maybe create some efficiencies, to help us measure quality of care better, how does Medicare at some point look at the investment that would take and how it fits into our various payment mechanisms? I think it links back to the quality discussion also, obviously, that we had earlier in our sessions this year. It's a complicated topic but I think one over the next two or three years that we'll need to address in addition to the specific devices.

MR. DeBUSK: Joe, what product falls in that category where there's no competition? Do you have something in mind?

DR. NEWHOUSE: Let's try erythropoietin.

MR. DeBUSK: In the drug area. In the supply industry we're profit neutral in what we try to do.

[Laughter.].

MR. HACKBARTH: Any other comments on this?

MR. DURENBERGER: Can i just clarify that? I like the idea of the value approach. I don't get the analogy with drinking water, so I think it ought to be explored.

DR. NEWHOUSE: How would you do it if --

MR. DURENBERGER: I don't want -- you're so smart I can't debate you on this.

DR. NEWHOUSE: Let me ask you this, how would you apply value-based purchasing to what the government show pay for erythropoietin? You could say it's a very useful drug, it's a great drug and we should cover; it should be available to --

MR. DURENBERGER: So how about drug eluting stents, or we can go on and on with -- there's a variety of technologies we're talking about. The question is, is there a process to determine how much we should pay for it.

DR. NEWHOUSE: Yes, that's it. But it's not, I think, going the route of trying to figure out what is the benefit to the patient and we would therefore pay something that equaled the benefit.

MR. DURENBERGER: I don't want to discourage the approach to value.

DR. NEWHOUSE: So again, distinguish coverage from payment.

MR. HACKBARTH: As I understand Joe, he's not in disagreement with the point that in making coverage decisions that we ought to take into account value. Then the next step is, okay, it's in, what do we to pay for it? His point is trying to determine the value of pay on that base basis probably doesn't lead us to the right place, so we need another method. As he said his preferred one, at least in the case where it's one source -- least dispreferred -- what he likes best of a bunch of difficult options is that we look at the return on investment that the developer has made in it and we agree on some number for that.

Now that has a lot of difficult technical issues, I imagine, in some right but it's different than saying we're going to pay for its value.

MR. DURENBERGER: We're comparing something new with something not so new. Something that's in the process.

DR. NEWHOUSE: Then that's fine. Then there's a good substitute and we can have competition.

MR. HACKBARTH: So an important feature of what Joe is saying is that when there's no alternative to it. This is new and there's no substitute, it's on patent, one supplier, et cetera. Those are special cases but important cases.

MR. DURENBERGER: Like bottled water as opposed to water in the tap.

[Laughter.]

MR. HACKBARTH: Any other comments? I think this is a very good chapter. Chantal, thank you for your work on it.